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STATE PLEASE PASS TO USTR FOR JCHOE-GROVES
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SUBJECT: AUSTRIA: SPECIAL 301 INPUT ON PHARMA SUBMISSION

REF: STATE 9475

¶1. (U) This message provides post's response to reftel request for input to the annual Special 301 review. The Pharmaceutical Research and Manufacturers of America Organization (PhRMA) has requested that the USG place Austria, as well as several other EU member states and Norway, on the Watch List because of market access and patent protection infringements.

¶2. (U) The pharmaceutical industry has been pressing the GoA for several years to improve its pricing and reimbursement process, which industry believes is inadequate. In an attempt to address industry concerns about a lack of transparency in the reimbursement process, the GoA introduced a new reimbursement system in 2004 with three "boxes" that indicate the status of approval and reimbursement for new and innovative drugs. Industry maintains that drugs are still not authorized entirely based on therapeutic values. Moreover, in the view of industry, the delay between market authorization and market access is very lengthy (397 days according to a study, which is the third longest period in the EU).

¶3. (U) In July 2007, the European Commission (EC) began proceedings against Austria for violating the EU-Transparency Directive (89/105/EEC). The European Court of Justice had already ruled against Austria on this matter in 2001. The EC maintains that Austrian law does not stipulate "objective and verifiable" criteria for the authorization process for innovative pharmaceuticals. The GoA argues that new legislation will come into force in 2008 and 2009 that meets the transparency criteria.

¶4. (U) Producers of generics traditionally have a strong lobby in Austria. Austria has seen an increasing number of patent infringements by generics producers in recent years. Embassy has received reports of at least four cases between 2003 and 2006, when the Austrian health insurance authorities approved a generic before the patent of the originator (in all cases UK companies) had expired. In two cases, the originator went to court and won. However, due to lengthy court proceedings, the companies had to lower the price of the pharmaceutical significantly to compete with the generic. Industry has demanded that the GoA establish a "patent-check" mechanism in the registration and reimbursement process.

¶5. (SBU) Embassy informed the Ministry of Economics (MoE) about the USG's 2008 Special 301 review and shared the PhRMA submission with them, per instructions from USTR. Our MoE contact claimed that industry's arguments have already been refuted. The contact said that the GoA will submit a comment on this issue to the Special 301 Committee by February 29.

¶6. (SBU) Comment: U.S. innovative pharmaceutical companies in Austria would welcome the inclusion of Austria on the Special 301 Watch List. Embassy shares industry's concerns, particularly on the patent protection issue, but also on the issue of non-transparency.

However, we are unable to provide a definite recommendation as to whether or not these shortfalls merit Austria's inclusion in the Special 301 Watch List, given the alleged legislative relief. We strongly recommend treating all EU countries in a consistent way, as most of PhRMA's complaints against EU member states appear to focus on similar IP infringement and market access issues.

YAP#